SE TITOUR 331/2) PTO TIMB 0651-0021 U.B. DERARI MENULB COMMERCE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

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68682-PCT-US/JPW/JW

ee 37 CFR 1.5)

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED May 14, 2003

PCT/US2004/015225 May 14, 2004 TITLE OF INVENTION COMBINATION THERAPY WITH GLATIRAMER ACETATE AND MITOXANTRONE FOR THE TREATMENT OF MULTIPLE SCLEROSIS APPLICANT(S) FOR DO/EO/US Timothy Vollmer Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). X A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). \mathbf{x} Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). X An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (unsigned) An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: (including Form PTO-1449 as Exhibit A and An Information Disclosure Statement under 37 CFR 1.97 and 1.98. cited references as Exhibits 1-5) 11. X An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. X A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer. U.S. Patent and Trademark Office, U.S.

#C20 Rec'd PCT/PTO 11 NOV 2005

PTO-1390 (Rev. 07-2005) Approved for use through 3/31/2007. OMB 0651-0021

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U.S. APPLICATION NO TITRIOWN, SECTOR (FR 1.5) INTERNATIONAL APPLICATION NO. ATTORNEY'S DOCKET NUMBER PCT/US2004/015225 68682-PCT-US/JPW/JW Return receipt postcard; and Express Mail Certificate of 20. Other items or information: Mailing dated November 11, 2005, bearing Express Mail Label No. EV 553660176 US The following fees have been submitted CALCULATIONS PTO USE ONLY 21. 🕱 300 Examination fee (37 CFR 1.492(c)) \$ 200 If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)......\$0 All other situations......\$200 Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by 100 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....\$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB......\$400 All other situations.....\$500 600 TOTAL OF 21, 22 and 23 = Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. Number of each additional 50 or fraction RATE **Total Sheets** Extra Sheets thereof (round up to a whole number) **0** /50 = 28 \$ 0 - 100 = x \$250 Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). NUMBER EXTRA RATE \$ CLAIMS NUMBER FILED x \$50 \$ Total claims - 20 = 250 25 5 Independent claims 3 - 3 = 0 \$200 \$ х 0 \$360 MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$ 0 850 **TOTAL OF ABOVE CALCULATIONS =** \$ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. SUBTOTAL = \$ 850 Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest \$ claimed priority date (37 CFR 1.492(i)). TOTAL NATIONAL FEE = \$ 850 Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied \$ by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property TOTAL FEES ENCLOSED = 850 Amount to be S refunded: Amount to be \$ charged

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A check in the amount of \$ 850.00 a. X to cover the above Please charge my Deposit Account No. in the amount of \$ A duplicate copy of this sheet is enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No.03-3125. A duplicate copy of this sheet is enclosed. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. SEND ALL CORRESPONDENCE TO: John P. White John P. White Cooper & Dunham LLP (Customer No. 23432) NAME 1185 Avenue of the Americas New York, New York 10036 28,678 United States of America **REGISTRATION NUMBER**

10/556454

1C20 Rec'd PCT/PTO 11 NOV-2005

Dkt. 68682-PCT-US/JPW/JW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Timothy Vollmer Applicant

Not Yet Known (national stage of PCT U.S. Serial No.

International Application No.

PCT/US2004/015225)

Filed Herewith

COMBINATION THERAPY WITH GLATIRAMER ACETATE AND MITOXANTRONE FOR THE TREATMENT OF MULTIPLE SCLEROSIS For

1185 Avenue of the Americas New York, New York 10036 November 11, 2005

Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

EXPRESS MAIL CERTIFICATE OF MAILING FOR ABOVE-IDENTIFIED APPLICATION

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I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee' service under 37 C.F.R. §1.10 on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Printed Name:

Respectfully submitted,

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